

**UNITED STATES DEPARTMENT OF COMMERCE****Patent and Trademark Office**Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/485, 163	06/07/95	BEAUDRY	G 37690-II-1-P

JOHN P WHITE  
COOPER & DUNHAM  
1185 AVENUE OF THE AMERICAS  
NEW YORK NY 10036

HM12/0309

EXAMINER	
LAZAR WESLEY, E	
ART UNIT	PAPER NUMBER
1646	32

**DATE MAILED:** 03/09/01

Please find below and/or attached an Office communication concerning this application or proceeding.

**Commissioner of Patents and Trademarks**

## Office Action Summary

Application No. <b>08/485,163</b>	Applicant(s) <b>Beaudry</b>
Examiner <b>Eliane Lazar-Wesley</b>	Group Art Unit <b>1646</b>

Responsive to communication(s) filed on Nov 14, 2000

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

### Disposition of Claims

Claim(s) 30-35 and 44-46 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 30-35 and 44-46 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims \_\_\_\_\_ are subject to restriction or election requirement.

### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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### **DETAILED ACTION**

1. The amendment filed November 14, 2000, has been entered. This amendment includes the communication that had been filed on June 08, 1999.

Claims 30-35 and 44-46 are under consideration.

#### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 30-35 and 44-46 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Elements required for practicing a claimed invention must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. When biological material is required to practice an invention, and if it is not so obtainable or available, the enablement requirements of 35 USC '112, first paragraph, may be satisfied by a deposit of the material. See 37 CFR 1.802.

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The specification does not provide a repeatable method for obtaining clone CD4-IgG2-pcDNA1 and it does not appear to be a readily available material. Deposit of the clone would satisfy the requirements of 35 USC '112, first paragraph.

*It is noted that Applicant has deposited the clone CD4-IgG2-pcDNA1 at ATCC (page 19 of the specification), but there is no indication in the specification as to public availability.*

If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 CFR 1.808.

If a deposit is not made under the terms of the Budapest Treaty, then an affidavit or Declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made at an acceptable depository and that the following criteria have been met:

- (a) during the pendency of the application, access to the deposit will be afforded to one determined by the Commissioner to be entitled thereto;
- (b) all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent;
- (c) the deposit will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material;
- (d) a viability statement in accordance with the provisions of 37 CFR 1.807; and
- (e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

In addition the identifying information set forth in 37 CFR 1.809(d) should be added to the specification. See 37 CFR 1.803-1.809 for additional explanation of these requirements.

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Applicant's attention is directed to M.P.E.P. §2400 in general, and specifically to §2411.05, as well as to 37 C.F.R. § 1.809(d), wherein it is set forth that "the specification shall contain the accession number for the deposit, the date of the deposit, the name and address of the depository, and a description of the deposited material sufficient to specifically identify it and to permit examination."

Applicant is reminded that the address of ATCC has changed and is now

ATCC  
10801 University Boulevard  
Manassas, VA20110-2209

*Claim Rejections - 35 USC § 103*

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
5. Claims 30-35 and 44-46 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Capon, US Patent 5,565,335, for the reasons of record in the Office action of August 07, 1997 (Paper #20).

Applicants arguments have been fully considered but have not been found persuasive for the reasons of record and the following reasons:

Applicants argue the criticality of the specific amino acid composition and structure of the CD4 portion and of the Ig portion of their chimera, and that Capon teaches away from the claimed construct. However, this is not persuasive because, while Capon's preferred embodiment does not have the exact structure claimed herein, the Capon reference was not applied in order to anticipate the

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claims, but has been applied to render the claims obvious, and Capon clearly envisions making chimeras using modified CD4 and immunoglobulin chains (see for example col.5, lines 26-32), teaches a CD4-IgG2 fusion protein (col.7, lines 47-49) and does not teach away from the claimed invention.

Applicants argue that their construct has unexpected properties, and refer to Exhibits 1 and 2. However, this argument cannot be considered, absent evidence being properly presented. If applicants wish to provide evidence for consideration by the Patent Office, applicants must provide a declaration according to Rule 1.132.

Applicants argue that their CD4-gamma2 chimeric heavy chain homodimer construct has unexpected properties, by referring to results published by Gauduin, Journal of Virology, 70(4):2586-2592, April 1996, and Capon, Nature 337:525-531, 9 February 1989, (Exhibits 3 and 4). Gauduin teaches a CD4-IgG2 construct that is more potent than sCD4 in ex-vivo neutralizing HIV-1, and Capon (Nature) teaches that sCD4 and CD4-IgG1 are equipotent in neutralization.. Applicants therefore concludes that "CD4-gamma2 is more potent than CD4-gamma1". However, this is not persuasive, because Applicants , in the specification and in their arguments against the Capon '335 patent, insist upon the criticality of the specific amino acid composition and secondary structure of their chimera for its function. The examiner could not clearly ascertain if the claimed CD4-gamma2 chimeric heavy chain homodimer, and "CD4-IgG2, a tetrameric human antibody prepared from a human IgG2 with replacement of each heavy- and light-chain variable region by the first and second domains of human CD4" disclosed by Gauduin, page 2586, col.2 lines 3-6, are identical in amino acid

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composition and structure /conformation, and therefore it is not clear if the activity of the claimed CD4-gamma2 chimeric heavy chain homodimer and of the cited CD4-IgG2 tetrameric antibody are identical or comparable.

6. No claim is allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eliane Lazar-Wesley, PhD, whose telephone number is (703) 305 4059. The examiner can normally be reached on Monday-Friday from 9:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 308 4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

ELW

March 08, 2001

EW



Lorraine Spector

LORRAINE SPECTOR  
PRIMARY EXAMINER